FDA Regulation of In Vitro Diagnostic Devices

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IVD Update

- People
- Workload
- Performance
- Current Activities
- Least Burdensome
- Strategic Plan

People

- New Commissioner -- Dr. McClellan
- New Deputy Commissioner – Dr. Crawford
- New Chief Counsel – Dan Troy
- Seasoned Center Director – Dr. Feigal
- New Center Organization – Linda Kahan and Lillian Gill

People

- Deputy Office Director -- Don St. Pierre
- Deputy Division Directors -- Josie Bautista, Jean Cooper, Freddie Poole
- AD for Special Programs -- Joe Hackett
- Regulatory Program Advisor -- James Woods (detail)
- Legal Advisor for Regulatory Affairs -- Terri Garvin (detail)

People -- Programs

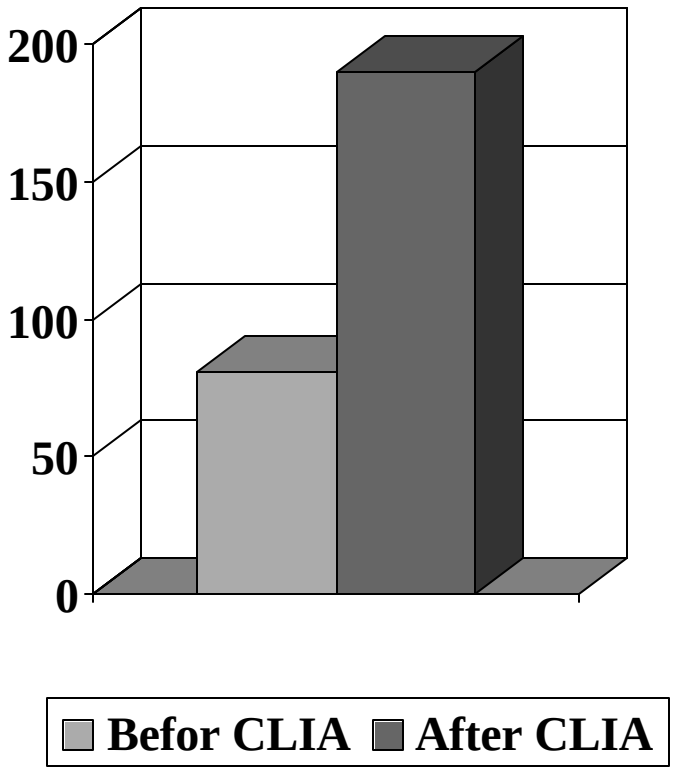
- Premarket Review
- CLIA categorization
- Genetics working group
- Bioterrorism initiatives
- TPLC initiative

Number of Original 510(k)s

	# Originals
FY98	1014
FY99	915
FY00	733
FY01	679
FY02	629

Replacement Reagents
February 2000 - November 2001

- 330 add to the records for Replacement Reagents
  - An average of 190 per year
  - Before CLIA the average was 81 per year



Decreased 510(k)s

- Liberalization in modifications policies
- Increased use of ASR rule
- Laboratory cost constraint environment

FY02 510(k) Review Stats

	n	FDA time	MFG time	Total time
Trad.	552	70	21	91
Abbrev.	11	63	23	86
Special	66	23	6	29
3rd Party	7	18	20	38

PMA Approvals

	Originals	Supplements
FY98	5	20
FY99	8	30
FY00	2	60
FY01	16	32
FY02	7 (221/45/266)	63

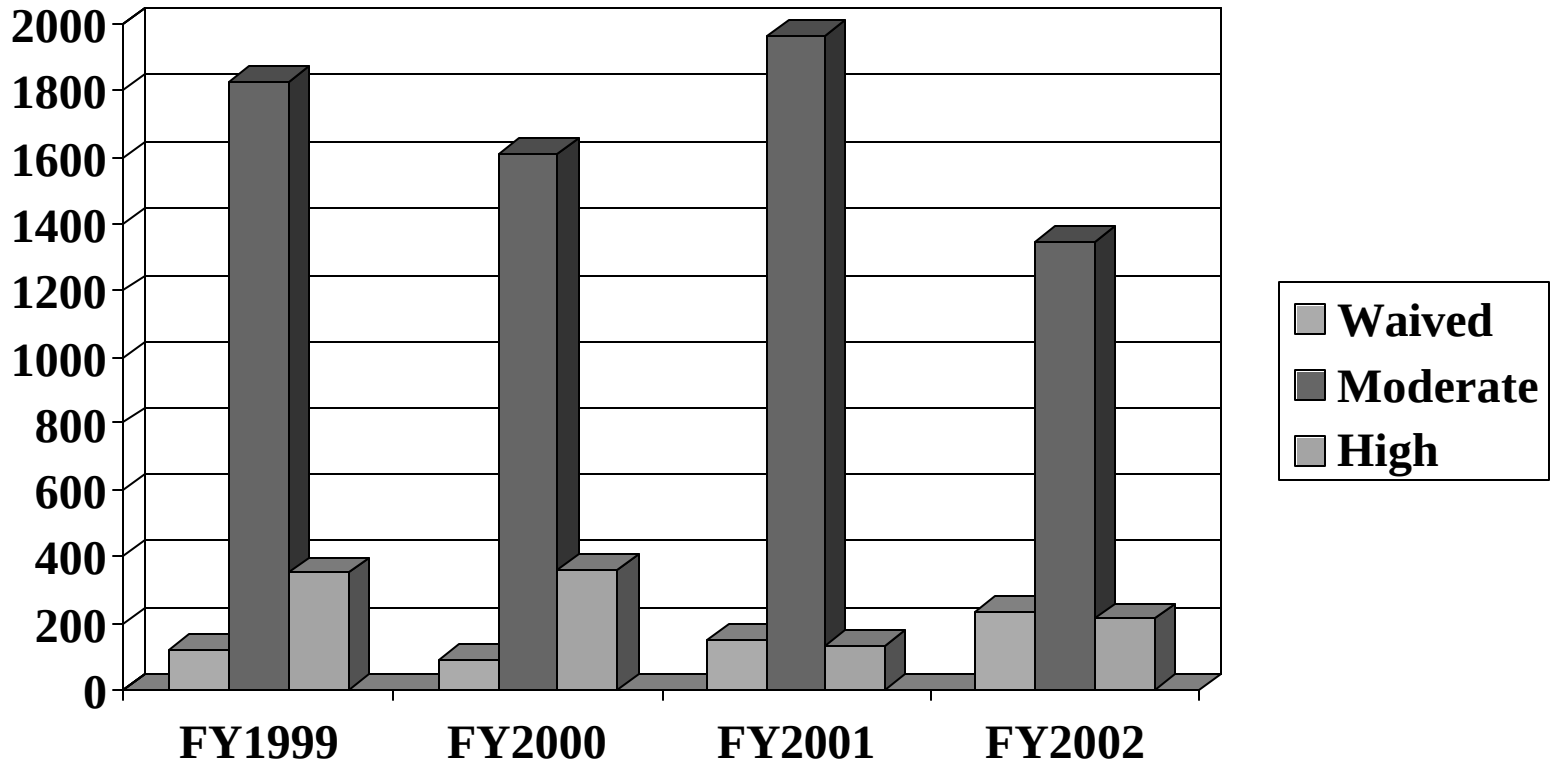
Approvals by Type of PMA/S

	Normal	Panel	Real-Time	30-day	Special
FY98	14	1	1	0	4
FY99	17	4	4	2	3
FY00	52	1	2	2	1
FY01	26	2	5	6	1
FY02	44	1	10	5	3

Other OIVD Documents

	Pre-IDE	Pre-IDE Supple.	IDE	IDE Supple.
FY98	46	4	6	12
FY99	55	10	1	11
FY00	64	11	3	8
FY01	85	16	1	10
FY02	87	30	4	9

CLIA Workload



CLIA Complexity Determinations

- Assigned to FDA in 1992
- Transferred to CDC in 1994
- Proposed rule in 1995 -- standards based approach requiring no inaccuracy
- Confounding language in FDAMA
- Interest in one stop shopping
- Transferred to FDA in 1999

Waiver Criteria

- Evolved over time
- Challenged by changing technology
- FDA public meeting -- broader criteria
- FDA guidance

CLIA Studies

- CMS pilot studies
- 32% labs lack instructions
- 32% have no QC
- 16% fail to follow instructions

Waiver Criteria

- CMS exerted authority
- Return to 1995 rule
- CMS working on refining authorities -- collaborative effort
- FDA active review following statute -- filtered through 1995 rule

Waiver Process is Complex

- Waiver by regulation -- 8 analytes
- Waiver through OTC -- a dozen analytes
- Waiver through 1995 rule criteria -- a dozen analytes

Non-Parallel

- OTC clearances are based on substantial equivalence standard
- Lay use equivalent to lab use
- Labeling is understandable
- Benefits outweigh risks

CLIA Program

- Awkward transition
- Current problem in non-congruent QC labeling
- High visibility device under consideration
- No final chapter

CLIA

- Need for education
- Opportunity for industry
- Opportunity for professional groups
- Opportunity for government

Genetics -- “home brews”

- “Home Brews” -- unregulated devices
- SACGT recommendations on the table
- FDA outlined possible responses – detailed action plan
- Risk based approach -- CBER
- New review tools

Pharmacogenomics

- Hackett initiative
- IVD version of Staff College
- Extensive internal and external outreach
- Two Round Tables -- Pharmacogenomics and TDM

Genetics Initiatives

- Final chapter not written
- ACLA meeting -- Dan Troy did indicate regulation remains an option
- Active exploration of how to pursue this

Diagnostics for Bioterrorism

- Diagnostics central
- CDRH not well funded
- Internal resource re-direction
- Independence

Diagnostics for Bioterrorism

- Complex regulatory issues and choices
- Complex scientific issues
- Fall out from environmental tests
- When is an environmental test diagnostic?

Antimicrobial Resistance Initiatives

- FDA not central, diagnostics are
- Area needing increased attention
- Inter-departmental plan in place
- Searching for mechanisms to aid technology transfer in this area
- Displaced by interest in bioterrorism

Industry Interests -- IVD Round Table

Quality Submissions

- IVD Workshop
- In conjunction with AMDM
- Unique and popular

Quality Guidances

- Guidances – Time and expertise intense
- Provide standardization
- Provide clarify
- Industry input
- FDA slow on uptake

Collaborative Problem Identification/Solving

- Alternative site testing the rage
- Physiological problem identified
- FDA called a panel
- Industry formed glucose working group
- Industry directed guidance
- Peer pressure drove labeling

Educational Outreach

- Clarify new programs
- Q and A’s
- Real Time PMA supplements
- De novo 510(k)s
- Pre-IDEs
- Posted on industry web pages

Future Milestone -- Labeling Initiatives

- Symbols
- International harmonized labeling -- ISO 212
- Better home use labeling
- Better labeling

Laboratory Interests -- Professional Round Table

Quality Submissions

- Clarification of program strengths and weaknesses
- Identification of collaborative activities
- Activist bridge AACC

Quality Guidances

- Less experience
- Rich perspective

Collaborative Problem Identification/Solving

- Communicate device issues
- Work with regulatory systems
- Develop better sharing of knowledge

Meet User Needs

- Heterogeneous community
- Variable resources
- Cost constraints
- Variable expectations

FDAMA

- Improved market access
- Least burdensome pathways
- Premarket to postmarket balance
- Increased interaction with industry

Least Burdensome

- Appropriate questions
- Appropriate thresholds
- Non-academic pursuits

Least Burdensome

- Matter of law
- Matter of policy
- Matter of spirit

Least Burdensome

- Two Guidance Documents
- Systems Approach -- ensure appropriate process applied to use of regulatory tools
- Review Guidance

Least Burdensome

- Review changes are profound
- Parallel genetics

Least Burdensome

- Shift to data summaries
- Shift to more focused labeling review
- Shift to use of clinical literature
- Shift to postmarket

Strategic Plan -- Goals

- Mission related
- Total Product Life Cycle
- Magnet for Excellence

Total Product Life Cycle

- Cradle to grave
- Seamless oversight

Intellectual Appeal

- **Premarket review limitation**
- Outdated law
- Snapshot approach
- Impact of scale-up
- Impact of wide-use

Intellectual Appeal

- **Postmarket review strengths**
- Quality system regulations
- Require quality assessment
- Require process controls
- Require corrective actions

Intellectual Appeal

- **Need for harmonization**
- IVD directive
- JCTLM
- NIST/NCI/CAP initiatives

Office of IVDs

- Product of cross office brain storming
- Not unique -- one program to promote TPLC
- Small number of players -- major structural change
- Merger of premarket with compliance and integration of postmarket into this unit

Office of IVDs

- Three divisions
- Compliance support staff
- Cross-office support

TPLC IVD Program

- Ideal target
- Stereotyped review issues
- Cadre of like minded scientists
- Rapidly emerging technologies
- Already multi-tasking

Office of IVDs

- What it means to you?
- Single organizational unit
- One stop shopping

Office of IVDs

- What it does not means to you?
- Change in premarket requirements
- Change in postmarket requirements

Office of IVDs

- What it could mean to you?
- Coordination improved
- Innovative programming encouraged
- Clearer expectations

Office of IVDs

- Objective -- TPLC
- Common technical base
- Faster response time
- Flatter more dynamic organization

Goals

- Increased transparency
- Uniform least burdensome approach
- Expedited technology transfer
- Improve connectivity and quality of work

Knowledge Based Initiative

- Internal sharing
- External sharing
- IVD Web Page

Patient Safety

- Transcend compliance and surveillance
- Emphasize education and information; enforcement when necessary
- Look at IVD specific refinements in existing programs

Patient Safety

- MedSun pilot
- Improved use of data inputs
- Laboratory safety tips
- Patient safety tips

Fortuitous Timing

- Changing health care environment
- Changing regulatory environment
- Changing administrative environment -- equation tipped toward access to technology
- Technological revolution -- numbers down but innovations up

Precepts

- Improved connectivity
- Improved communication
- Improved assessment
- Expanded leveraging
- Search for forest instead of trees

Looking for Input

- Function
- Structure
- Introspective
- Reality checks

Core Mission

- Promote public health
- Apply good science
- Evolving program
- Relevant, focused, safe and effective